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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,247	04/02/2007	Reed Gamble	330499.00050	3023

27160 7590 03/27/2008  
PATENT ADMINISTRATOR  
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EXAMINER
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GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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03/27/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/573,247	<b>Applicant(s)</b> GAMBLE, REED	
	<b>Examiner</b> KONATA M. GEORGE	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/23/06; 7/19/06</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Claims 1-30 are pending in this application.

#### ***Drawings***

The drawing(s) filed under 37 CFR 1.184 or 1.152 are accepted by the examiner.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on March 23, 2006 and July 19, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants use the phrase "greater than or equal to" in the claims when describing UV protection factor. It is unclear to the examiner if it is "greater than" or "equal to" are the intended values.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-5, 18-20, 23-25 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Jenkins (US 5,352,457).**

Jenkins discloses in Figure 1, a transdermal device comprising a backing adjacent to an adhesive layer. Column 5, lines 32-36 teach examples of materials that can be used as the backing layer such as metallized polyester laminate. Applicant claims in claim 1, that the patch is used for “reducing exposure to ultraviolet (UV) radiation”. The examiner views this recitation as intended use language in a composition claim. With respect to the intended use in a claim for a composition, a statement of intended use is of little patentable weight unless it specifically alters one or more ingredients of said composition. *In re Madder et al.* 143 USPQ 248. Although Jenkins is silent with respect to one of the layers being opaque to UV radiation it the position of the examiner that this limitation is met. It is widely known that metals reflect visible light as well as UV radiation. Therefore, because the backing layer comprise metal the limitation is inherent.

**Claims 1-5, 18-20, 23-25 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Farinas et al. (US 5,906,830).**

Farinas et al. (hereafter Farinas) disclose in Figure 1, a transdermal device comprising a backing adjacent to an adhesive layer. Column 8, line 59 through column 9, line 15 teach examples of materials that can be used as the backing layer. It is taught that the backing layer can be metallized. Applicant claims in claim 1, that the patch is used for “reducing exposure to ultraviolet (UV) radiation”. The examiner views this recitation as intended use language in a composition claim. With respect to the intended use in a claim for a composition, a statement of intended use is of little patentable weight unless it specifically alters one or more ingredients of said composition. *In re Madder et al.* 143 USPQ 248. Although Farinas is silent with respect to one of the layers being opaque to UV radiation it the position of the examiner that this limitation is met. It is widely known that metals reflect visible light as well as UV radiation. Therefore, because the backing layer comprise metal the limitation is inherent.

**Claims 1-5, 16-21, 23-26 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Banerjee (US 4,692,462).**

Banerjee discloses in Figures 3-5, a transdermal device comprising a backing adjacent to an adhesive layer. Column 3, lines 39-44 teach examples of materials that can be used as the backing layer such as aluminum foil. Column 3, lines 47-48 also disclose that the drug composition of the patch can be permitted to cool and gel or solidify. Applicant claims in claim 1, that the patch is used for “reducing exposure to ultraviolet (UV) radiation”. The examiner views this recitation as intended use language

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in a composition claim. With respect to the intended use in a claim for a composition, a statement of intended use is of little patentable weight unless it specifically alters one or more ingredients of said composition. *In re Madder et al.* 143 USPQ 248. Although Banerjee is silent with respect to one of the layers being opaque to UV radiation it the position of the examiner that this limitation is met. It is widely known that metals reflect visible light as well as UV radiation. Therefore, because the backing layer comprise metal the limitation is inherent.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 6-15, 22 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins (US 5,352,457) or Farinas et al. (US 5,906,830) or**

**Banerjee (US 4,692,462) in view of Edwards et al. (US 6,037,280) and Woods (WO 02/059407).**

Applicant claims a patch comprising a first layer that is adhesive and a second layer comprising a material adjacent to the first layer, wherein at least one of the first and second layers is opaque to UV radiation.

***Determination of the scope and content of the prior art***

**(MPEP §2141.01)**

Jenkins discloses in Figure 1, a transdermal device comprising a backing adjacent to an adhesive layer. Column 5, lines 32-36 teach examples of materials that can be used as the backing layer such as metallized polyester laminate.

Farinas disclose in Figure 1, a transdermal device comprising a backing adjacent to an adhesive layer. Column 8, line 59 through column 9, line 15 teach examples of materials that can be used as the backing layer. It is taught that the backing layer can be metallized.

Banerjee discloses in Figures 3-5, a transdermal device comprising a backing adjacent to an adhesive layer. Column 3, lines 39-44 teach examples of materials that can be used as the backing layer such as aluminum foil. Column 3, lines 47-48 also disclose that the drug composition of the patch can be permitted to cool and gel or solidify.

***Ascertainment of the difference between the prior art and the claims***

**(MPEP §2141.02)**

Jenkins, Farinas or Banerjee do not disclose the addition of a UV radiation blocking agent or calendering the blocking agent or the shape of the patch being circular. It is for this that Edwards et al. and Woods are joined.

Edwards teaches the use of UV blocking particles on fabrics for the purpose of deflecting, reflecting, absorbing and/or scattering ultraviolet rays (col. 2, lines 10-15). Column 2, lines 34-51 disclose examples of the UV blocking particles, including metal oxides and its salts.

Woods teaches a method for calendering fabrics for improving the performance of UV blocking agents.

***Finding of prima facie obviousness***

***Rational and Motivation (MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Edwards and Woods in the invention of Jenkins, Farinas or Banerjee to arrive at the claimed invention. As mentioned above Jenkins, Farinas or Banerjee teaches the patch as claimed with the addition of the UV blocking agent or calendering the patch. The addition of an UV blocking agent would have been obvious to one of ordinary skill in the art as an additional means of blocking the harmful effects of UV radiation. It would have been within the skill of one in the art after the addition of additional UV protection, to improve the performance. To do so one



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could look to the teachings of Woods. With respect to the shape of the patch, one of ordinary skill in the art could design the patch in any manner that would suit the purpose of the patch, which could include the shape of the patch.

### ***Conclusion***

Claims 1-30 are rejected.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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